DATE 30 Sep 03

USAMMDA INFORMATION PAPER

PRODUCT: HEMORRHAGE CONTROL DRESSING

DESCRIPTION: The Hemorrhage Control Dressing (Chitosan Dressing [CD]) is intended to provide a revolutionary improvement in the control of severe life-threatening hemorrhage. The goal is to have a dressing that, when applied with direct pressure, will stop severe arterial and/or venous bleeding. Utilizing combinations of biologically compatible components that can be put on, or into a casualty, it is intended for use by the combat medic/combat lifesaver and other medical personnel on the battlefield.

PROGRAM RELEVANCE TO THE ARMY: This product supports both the core mission of the Army and the Army Transformation. Of the Army's core competencies, this product supports "Forcible Entry Operations," "Sustained Land Dominance," and "Support of Civil Authorities." In any conflict or civilian disaster, it is an unfortunate fact that there will be casualties with severe bleeding. This product is intended to save soldiers' lives in those situations. The aid man and the combat lifesaver will use it far forward to reduce bleeding and allow the casualty to be evacuated to available medical assets further back, again reducing the logistical burden far forward. This product supports Future Operational Capabilities: MD-02-001 Clearing the Battlefield and MD-02-002 Hospitalization.

ISSUES/ACTIONS:

- Approximately 2700 CDs have been shipped in support of Operation Enduring Freedom and Operation Iraqi Freedom.
- Significant progress has been made on previous Good Manufacturing Practices (GMP)-related issues. Major quality control and scale-up issues have been resolved and mass-produced CDs are being released. Increased production capacity is needed to keep up with demand.
- The manufacturer recently received Food and Drug Administration (FDA) 510(k) clearance to market the CD with labeling for non-prescription use.
- The withdrawal of the HD IND Battlefield Protocol has focused attention on the CD's suitability for internal use. The manufacturer is currently developing an absorbable backing for the CD, however, *in vivo* pre-clinical testing of an internal use CD prototype remains to be done. The U.S. Army Institute of Surgical Research intends to conduct internal use testing as part of a head-to-head evaluation of the CD and the HD.
- The manufacturer is currently working to obtain FDA clearance for temporary control of internal bleeding.

ADDITIONAL INFORMATION:

BPL # 442
DA PROJECT/TASK: Trauma Management – PE/PROJ 643807/836AJ
MAMP RANK: 1/36
ARMY ORD: Approved, 28 April 1999
SOCOM ORD: Approved, 15 June 1998

SCHEDULE:
FRP 1QFY07

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